PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/618,531	Confirmation No.: Unassigned
Applicant:	Phillip A. Furman	
Filed:	July 11, 2003	
TC/A.AU.:	Unassigned	
Examiner:	Unassigned	
Docket No.:	04674.105070 TRI 1016 US	
Customer No.:	20786	
Title:	Combination Therapies with L-FMAU for the Treatment of Hepatitis B Virus Infection	

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Transmittal of Information Disclosure Statement

Sir:

The citation of information on the attached Form PTO-1449, "List of Art Cited by Applicant," is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each reference is being submitted as part of this Information Disclosure Statement. The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

Because this Information Disclosure Statement is being submitted before the mailing of a first Office action on the merits as under 37 CFR §1.97(b)(3) the Applicant does not believe that any fees are due; however, the Commissioner is hereby authorized to charge any fees due or credit any overpayment to Deposit Account No. 11-0980.

Respectfully submitted,

Sherry M. Knowles, Esq.
Reg. No. 33,052

King & Spalding, LLP
191 Peachtree Street, N.E., Atlanta, GA 30303
Office: (404)572-4600/ Fax: 404-572-5145

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 11, 2004.

Brent R. Bellows

Please type a plus sign (+) inside this box →

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	7

Complete if Known	
Application Number	10/618,531
Filing Date	07-11-2003
First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016

3397510_2

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. [1]	U.S. Patent Document Number	Kind Code [2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	3,798,209		Witkowski *et al.*	03-19-1974	
	AB	RE29,835		Witkowski *et al.*	11-14-1978	
	AC	5,075,445		Jarvest *et al.*	12-24-1991	
	AD	5,142,051	A	Holy *et al.*	08-25-1992	
	AE	5,444,063	A	Schinazi	08-22-1995	
	AF	5,539,116	A	Liotta *et al.*	07-23-1996	
	AG	5,565,438	A	Chu *et al.*	10-15-1996	
	AH	5,567,688	A	Chu *et al.*	10-22-1996	
	AI	5,587,362	A	Chu *et al.*	12-24-1996	
	AJ	5,641,763	A	Holy *et al.*	06-24-1997	
	AK	5.674,841	A	Pragnell *et al.*	10-07-1997	
	AL	5,674,849	A	Twist *et al.*	10-07-1997	
	AM	5,684,010	A	Schinazi *et al.*	11-04-1997	
	AN	5,684,153	A	Geen *et al.*	11-04-1997	
	AO	5,703,058	A	Schinazi *et al.*	12-30-1997	
	AP	5,767,102	A	Draper *et al.*	06-16-1998	
	AQ	5,767,122	A	Chu *et al.*	06-16-1998	
	AR	5,808,040	A	Chu *et al.*	09-15-1998	
	AS	5,814,639	A	Liotta *et al.*	09-29-1998	
	AT	5,834,474	A	Schinazi	11-10-1998	
	AU	5,905,070	A	Schinazi *et al.*	05-18-1999	
	AV	5,914,331	A	Liotta *et al.*	06-22-1999	
	AW	5,990,093	A	Schinazi *et al.*	11-23-1999	
	AX	6,194,388	B1	Krieg *et al.*	02-27-2001	
	AY	6,194,391	B1	Schinazi *et al.*	02-27-2001	
	AZ	6,207,646	B1	Krieg *et al.*	03-27-2001	
	AAA	6,218,371	B1	Krieg *et al.*	04-17-2001	
	AAB	6,225,292	B1	Raz *et al.*	05-01-2001	
	AAC	6,232,300	B1	Schinazi *et al.*	05-15-2001	
	AAD	6,239,116	B1	Krieg *et al.*	05-29-2001	
	AAE	6,339,068	B1	Krieg *et al.*	01-15-2002	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ⊞

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 7

Complete if Known	
Application Number	10/618,531
Filing Date	07-11-2003
First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016 US

3397510_2

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. [1]	U.S. Patent Document Number	Kind Code [2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	BA	6,406,705	B1	Davis *et al.*	06-18-2002	
	BB	6,562,798	B1	Schwartz	05-13-2003	
	BC	6,589,940	B1	Raz *et al.*	07-08-2003	
	BD	20020098199	A1	Van Nest *et al.*	07-25-2002	
	BE	20030091599	A1	Davis *et al.*	05-15-2003	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. [1]	Foreign Patent Document Office [3]	Number	Kind Code [2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T [6]
	BF	DE	4,224,737	A1	Herbert Schott	02-03-1994		
	BG	EPA	0,494,119	A1	IAF Biochem Int'l.	08-07-1992		
	BH	WO	92/18517	A1	Yale Univ.; U. Ga. R. F.	10-29-1992		
	BI	WO	94/09793	A1	Emory University	05-11-1994		
	BJ	WO	95/07086	A1	Emory Univ.; CNRS; UAB R.F.	03-16-1995		
	BK	WO	95/07287	A1	CNRS	03-16-1995		
	BL	WO	95/20595	A1	U. Ga. Res. Found.; Yale Univ.	08-03-1995		
	BM	WO	95/32984	A1	Boehringer Mannheim	12-07-1995		
	BN	WO	96/13512	A2	Genencor International	05-09-1996		
	BO	WO	96/22778	A2	Emory University	08-01-1996		
	BP	WO	96/40164	A1	Emory; UAB Res. F.; CNRS	12-19-1996		
	BQ	WO	97/28259	A1	University of California	08-07-1997		
	BR	WO	98/16247	A1	University of California	04-23-1998		
	BS	WO	98/23285	A1	SmithKline Beecham	06-04-1998		
	BT	WO	98/55495	A2	Dynavax Technologies	12-10-1998		
	BU	WO	99/05157	A1	Univ. of Georgia Res. Found.	02-04-1999		
	BV	WO	99/05158	A1	Univ. of Georgia Res. Found.	02-04-1999		
	BW	WO	99/11275	A2	University of California	03-11-1999		
	BX	WO	99/62923	A2	Dynavax Technologies	12-09-1999		
	BY	WO	99/66936	A1	Emory; Novirio Pharm. (Idenix)	12-20-1999		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ⊞

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	3	of	7

Complete if Known	
Application Number	**10/618,531**
Filing Date	**07-11-2003**
First Named Inventor	**Phillip A. Furman**
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	**04674.105070 TRI 1016 US**

3397510_2

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. [1]	Foreign Patent Document Office [3]	Number	Kind Code [2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	CA	WO	00/16804	A1	Dynavax Technologies	03-30-2000		
	CB	WO	00/09531	A2	Novirio Pharm. (Idenix), CNRS	02-24-2000		
	CC	WO	00/21556	A1	Dynavax Technologies	04-20-2000		
	CD	WO	00/25797	A1	Triangle Pharmaceuticals	05-11-2000		
	CE	WO	01/12223	A2	Dynavax Technologies	02-22-2001		
	CF	WO	01/22972	A2	U. Iowa R.F.; Coley Pharm.	04-05-2001		
	CG	WO	01/22990	A2	Coley Pharm.; U. Iowa R.F.	04-05-2001		
	CH	WO	01/68077	A2	Dynavax Technologies	09-20-2001		
	CI	WO	01/68078	A2	Dynavax Technologies	09-20-2001		
	CJ	WO	01/68116	A2	Dynavax Technologies	09-20-2001		
	CK	WO	01/68117	A2	Dynavax Technologies	09-20-2001		
	CL	WO	01/68143	A2	Dynavax Technologies	09-20-2001		
	CM	WO	01/68144	A2	Dynavax Technologies	09-20-2001		
	CN	WO	01/72294	A2	Georgetown; Cornell; U.Ga.	10-04-2001		
	CO	WO	01/95935	A1	Ottawa Health R.I.; Coley Ph.	12-20-2001		
	CP	WO	02/052002	A2	Dynavax Technologies	07-04-2002		
	CQ	WO	02/068058	A2	Triangle Pharmaceuticals	09-06-2002		
	CR	WO	02/069369	A2	Coley Pharmaceutical	09-06-2002		
	CS	WO	02/079213	A1	Triangle Pharmaceuticals	10-10-2002		
	CT	WO	03/000922	A2	Dynavax Technologies	01-03-2003		
	CU	WO	03/012061	A2	Coley Pharm.; Max Delbruck C.	02-13-2003		
	CV	WO	03/014316	A2	Dynavax Technologies	02-20-2003		
	CW	WO	03/015711	A2	Coley Pharmaceutical	02-27-2003		
	CX	WO	03/031573	A2	Coley Pharmaceutical	04-17-2003		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ⊞

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	4	of	7

Complete if Known	
Application Number	**10/618,531**
Filing Date	**07-11-2003**
First Named Inventor	**Phillip A. Furman**
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	**04674.105070 TRI 1016 US**

3397510_2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	DA	AGUESSE-GERMON, *et al.*, "Inhibitory effect of 2'-fluoro-5-methyl-b-L-arabinofuranosyl-uracil on duck hepatitis B virus replication," *Antimicrob. Agents Chemother.*, 42(2):369–376 (February 1998).	
	DB	AHMED, S.N.S., *et al.*, "Early detection of viral resistance by determination of hepatitis B virus polymerase mutations in patients treated by lamivudine for chronic hepatitis B," *Hepatology*, 32(5):1078-1088 (November 2000)	
	DC	ALLEN, M. I., *et al.*, "Identification and characterization of mutations in hepatitis B virus resistant to lamivudine," *Hepatology* 27(6):1670–1677 (June 1998).	
	DD	BALLAS, Z.K., *et al.*, "Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA," *The Journal of Immunology*, 157:1840-1845 (1996).	
	DE	CHAYAMA, K., *et al.* "Emergence and takeover of YMDD motif mutant hepatitis B virus during long-term lamivudine therapy and re-takeover by wild type after cessation of therapy, *Hepatology* 27(6):1711–1716 (June 1998).	
	DF	CHANG, C.-N., *et al.*, "Deoxycytidine deaminase-resistant stereoisomer is the active form of (+)-2'.3'-dideoxy-3'-thiacytidine in the inhibition of hepatitis B virus replication," *Journal of Biological Chemistry*, 267(20):13938-13942 (1992).	
	DG	CHIN, R., *et al.*, "In vitro susceptibilities of wild-type or drug-resistant hepatitis B virus to (-)-β-D-2,6-diaminopurine dioxolane and 2'-fluoro-5-methyl-β-L-arabinofuranosyluracil," *Antimicrob. Agents Chemother.*, 45(9):2495–2501 (September 2001).	
	DH	CHOW, Y.-K., *et al.*, "Use of evolutionary limitations of HIV-1 multidrug resistance to optimize therapy," *Nature*, 361:650–654 (1993).	
	DI	COLLEDGE, D., *et al.*, "Synergistic inhibition of hepadniviral replication by lamivudine in combination with penciclovir *in vitro*," *Hepatology* 26(1):216–225 (July 1997).	
	DJ	COLLEDGE, D., *et al.*, "In vitro antihepadnaviral activities of combinations of penciclovir, lamivudine, and adefovir," *Antimicrobial Agents and Chemotherapy*, 44(3):551-560 (March 2000).	
	DK	COWDERY, J.S., *et al.*, "Bacterial DNA induces NK cells to produce IFN-γ in vivo and increases the toxicity of lipopolysaccharides," *J. Immunol.*, 156:4570-4575 (1996).	
	DL	CULLEN, J.M., *et al.*, "In vivo antiviral activity and pharmacokinetics of (-)-*cis*-5-fluoro-1-(2-(hydroxymethyl)-1,3-oxathiolan-5-yl)cytosine in woodchuck hepatitis virus-infected woodchucks" *Antimicrob. Agents Chemother.* 41(10):2076-2082 (October 1997).	
	DM	DU, J., *et al.*, "A practical synthesis of L-FMAU from L-arabinose," *Nucleosides and Nucleosides*, 18(2):187-195 (1999).	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box → ⊞

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	5	of	7

Complete if Known	
Application Number	10/618,531
Filing Date	07-11-2003
First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016 US

3397510_2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	EA	FURMAN et al., "The Anti-Hepatitis B Virus Activities, Cytotoxicities, and Anabolic Profiles of the (-) and (+) Enantiomers of *cis*-5-Fluoro-l-{2-(Hydroxymethyl)-1,3-oxathiolane-5-yl}-Cytosine" *Antimicrobial Agents and Chemotherapy*, 36(12):2686-2692 (December 1992).	
	EB	GÁLVEZ, J., *et al.*, "Topological approach to analgesia," *J. Chem. Inf. Comput. Sci.*, 35(5):1198-1203 (1994).	
	EC	GISH, R.G., *et al.*, "Dose range study of pharmacokinetics, safety, and preliminary antiviral activity of emtricitabine in adults with hepatitis B virus infection," *Antimicrob. Agents Chemother.*, 46(6):1734–1740 (June 2002).	
	ED	GUIDOTTI, L.G, *et al.*, "Noncytopathic clearance of lymphocytic choriomeningitis virus from the hepatocyte," *J. Exp. Med.*, 189:1555-1564 (1999).	
	EE	GUO, J.-T., *et al.*, "Apoptosis and regeneration of hepatocytes during recover from transient hepadnavirus infections" *J. Virol.*, 74:1495-1505 (2000).	
	EF	KLINMAN, D.M., *et al.*, "Contribution of CpG motifs to the immunogenicity of DNA vaccines, " *J. Immunol.*, 158(8):3635-3639 (April 15, 1997).	
	EG	KORBA, B.E., *et al.*, "Enhanced antiviral benefit of combination therapy with lamivudine and famciclovir against WHV replication in chronic WHV carrier woodchucks," *Antivir. Res.* 45:19–32 (2000).	
	EH	KORBA, B.E., *et al.*, "Effect of oral administration of emtricitabine on woodchuck hepatitis virus replication in chronically infected woodchucks," *Antimicrob. Agents Chemother.*44(6):1757–1760 (June 2000).	
	EI	KRIEG, A.M., "Leukocyte stimulation by oligodeoxynucleotides," Chapter 24 in *Applied Antisense Oligonucleotide Technology,* C.A. Stein and A.M. Krieg, Eds., Wiley-Liss, Publishers, New York (1998), pp. 431-448.	
	EJ	LEUNG, N. W., *et al.*, "Extended lamivudine treatment in patients with chronic hepatitis B enhances hepatitis B e antigen seroconversion rates: Results after 3 years of therapy," *Hepatology* 33(6):1527–1532 (June 2001).	
	EK	LIN, T.-S., *et al.*, "Synthesis and antiviral activity of various 3'-azido analogues of pyrimidine deoxyribonucleosides against human immunodeficiency virus (HIV-1, HTLV-III/LAV), *J. Med. Chem.*, 31(2):336-340 (1988).	
	EL	LIPFORD, G.B., *et al.*, "CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: A new class of vaccine adjuvants," *Eur. J Immunol.* 27:2340-2344 (1997).	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box → ⊞

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	6	of	7

Complete if Known	
Application Number	10/618,531
Filing Date	07-11-2003
First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016 US

3397510_2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	FA	LOK, A.S.F., and McMAHON, B.J., "Chronic Hepatitis B," AASLD Practice Guidelines, in *Hepatology*, 1225-1241 (December 2001).	
	FB	MAHMOUDIAN, M., "Quantitative structure-activity relationships (QSARs) of pyrimidine nucleosides as HIV-1 antiviral agents," *Pharm. Research*, 8(1):43-46 (1991).	
	FC	MASON, W.S., *et al.*, "Lamivudine therapy of WHV-infected woodchucks," *Virology*, 245:18–32 (1998).	
	FD	MELEGARI, M., *et al.*, "Hepatitis B virus mutants associated with 3TC and famciclovir administration are replication defective," *Hepatology* 27(2):628–633 (February 1998).	
	FE	MENNE, S., *et al.*, "Immunization with surface antigen vaccine alone and after treatment with 1-(2-fluoro-5-methyl-β-L-arabinofuranosyl)-uracil (L-FMAU) breaks humoral and cell-mediated immune tolerance in chronic woodchuck hepatitis virus infection," *J. Virology*, 76(11):5305-5314 (June 2002).	
	FF	NOWAK, M.A., *et al.*, "Viral dynamics in hepatitis B virus infection," *Proc. Natl. Acad. Sci. USA* 93:4398–4402 (April 1996).	
	FG	ONO, S. K., *et al.*, "The polymerase L528M mutation cooperates with nucleotide binding-site mutations, increasing hepatitis B virus replication and drug resistance," *J. Clin. Investig.*, 107:449–455 (2001).	
	FH	PEEK et al., "Antiviral activity of clevudine [L-FMAU, (1(2-fluoro-5-methyl-beta, L-arabinofuranosyl) uracil)] against woodchuck hepatitis virus replication and gene expression in chronically infected woodchucks (Marmota monax)" *Hepatology* 2001, *33*, 254-66.	
	FI	PISETSKY, D.S., "The immunological properties of DNA," *The Journal of Immunology*, 156:421-423 (1996).	
	FJ	RISTIG, M.B., *et al.*, "Tenofovir disoproxil fumarate therapy for chronic hepatitis B in Human Immunodeficiency Virus / Hepatitis B Virus-coinfected individuals for whom interferon-α and lamivudine therapy have failed," *J. Infectious Diseases*, 186:1844-1847 (December 15, 2002).	
	FK	ROMAN, M., *et al.*, "Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants," *Nature Med.*, 3(8):849-854 (August 1997).	
	FL	SATO, Y., *et al.*, "Immunostimulatory DNA sequences necessary for effective intradermal gene immunization," *Science*, 273(5273):352-354 (July 19, 1996).	
	FM	SEIGNE`RES, B., *et al.*, "Inhibitory activity of dioxolane purine analogs on wild-type and lamivudine-resistant mutants of hepadnaviruses," *Hepatology* 36(3):710–722 (September 2002).	
	FN	SEIGNE`RES, B., *et al.*, "Evolution of Hepatitis B virus polymerase gene sequence during famciclovir therapy for chronic hepatitis B," *J. Infect. Dis.*, 181:1221–1233 (April 2000).	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box → ☒

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	7	of	7

Complete if Known	
Application Number	10/618,531
Filing Date	07-11-2003
First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016 US

3397510_2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	GA	SEIGNE`RES, B., *et al.*, "Duck hepatitis B virus polymerase gene mutants associated with resistance to lamivudine have a decreased replication capacity in vitro and in vivo," *J. Hepatol.* 34:114–122 (2001).	
	GB	SEIGNÈRES, B., *et al.*, "Effects of pyrimidine and purine analog combinations in the duck Hepatitis B Virus infection model," *Antimicrobial Agents and Chemotherapy*, 47(6):1842-1852 (2003).	
	GC	SHIMADA, S., *et al.*, "*In vivo* augmentation of natural killer cell activity with a deoxyribonucleic acid fraction of BCG," *Jpn. J. Cancer Res (Gann)*, 77:808-816 (August 1986).	
	GD	SNYDER, S., *et al.*, "The triple combination indinavir-zidovudine-lamivudine is highly synergistic," *Antimicrob. Agents Chemother.*, 44(5):1051–1058 (April 2000).	
	GE	STUYVER, L. J., *et al.*, "Nomenclature for antiviral-resistant human hepatitis B virus mutations in the polymerase region," *Hepatology* 33(3):751–757 (March 2001).	
	GF	TSAI, C.-H., *et al.*, "Effect of anti-HIV 2'-b-fluoro-2',3'-dideoxynucleoside analogs on the cellular content of mitochondrial DNA and on lactate production," *Biochem. Pharmacol.*, 48(7):1477-1481 (1994).	
	GG	VILLAHERMOSA, M. L., *et al.*, "Synergistic inhibition of HIV-1 reverse transcriptase by combinations of chain-termination nucleotides," *Biochemistry* 36:13223–13231 (1997).	
	GH	Von JANTA-LIPINSKI, M., *et al.*, "Newly synthesized L-enantiomers of 3'-fluoro-modified β-2'-deoxyribonucleoside 5'-triphosphates inhibit hepatitis B DNA polymerases but not the five cellular DNA polymerases α, β, γ, δ, and ε nor HIV-1 reverse transcriptase," *J. Med. Chem.*, 41(12):2040-2046 (1998).	
	GI	YAMAMOTO, S., *et al.*, "Unique palindromic sequences in synthetic oligonucleotides are required to induce INF and augment INF-mediated natural killer activity," *The Journal of Immunology*, 148:4072-4076 (1992).	
	GJ	YING, C., *et al.*, "Inhibition of the replication of the DNA polymerase M550V mutation variant of human Hepatitis B Virus by adefovir., tenofovir, L-FMAU, DAPD, penciclovir and lobucavir," *J. Viral Hepatitis*, 7:161-165 (2000).	
	GK	ZHU, Y., *et al.* "Kinetics of hepadnavirus loss from the liver during inhibition of viral DNA synthesis" *J. Virol.*, 75(1):311-22 (2001).	
	GL	ZOULIM, F., "Evaluation of novel strategies to combat hepatitis B virus targetting [sic] wild-type and drug-resistant mutants in experimental models," *Antivir. Chem. Chemother.*,12(Suppl. 1):131–142 (2001).	

3397510_2

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.